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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,480	08/13/2002	Robert Heger	49619	4809
7590	08/24/2004			
KEIL & WEINKAUF 1350 CONNECTICUT AVE., N.W. WASHINGTON, DC 20036			EXAMINER SPEAR, JAMES M	
			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/857,480

**Applicant(s)**

HEGER ET AL.

**Examiner**

James M Spear

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

1. In view of the Brief On Appeal filed on 05 May 2004, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for particular polymers and polymer containing composition, does not reasonably provide enablement for any polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
4. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112 first paragraph have been described in *In re Wands*, USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1. The Nature of the

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invention. 2. The State of the prior art. 3. The relative skill of those in the art. 4. The predictability or unpredictability of the art. 5. The breadth of the claims. 6. The amount of direction or guidance presented. 7. The presence or absence of working examples. 8. The quantity of experimentation necessary. 1. The claims are to a process requiring 2 distinct polymer preparations, however there is no evidence presented to determine differences between the two 2. The state of the art is considered high because the general process is known. 3. The relative skill of those in the art is high. 4. The predictability of the art is considered high. 5. The claims are very broad because virtually any polymer is encompassed by the claims. 6. There is little guidance presented with respect to the compact jet utilized to spray the polymer compositions. No apparatus is disclosed nor are there any disclosures of settings, temperature ranges, pressures, spraying ranges or other data considered necessary to practice the invention mixing step with a compact jet spray. Applicants disclose vigorous stirring, or shaking as well as spraying with a compact jet however the examples appear directed to stirring or shaking as a mixing means. There is no description of the compact jet or its use in processing other than the general disclosure on page 8, line 45 through page 9, line 2. 7. While there are examples presented, the examples do not appear to describe the process claimed. 8. The quantity of experimentation necessary is considered extensive. What applicants disclose as suitable polymers on page 4, lines 11-30 are not considered to be all polymers. While whole milk or skim milk may contain some polymer they are not generally considered to be polymers. No direction or guidance is disclosed for determining what properties or relationships the compounds

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have to allow them all to be grouped as polymers. When the above factors are weighed, it is the examiners position that one skilled in the art could not practice the invention without undue experimentation.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 recites the limitation "the active ingredient/polymer solution or precipitate" and "the polymer coating material" in lines 4-6. There is insufficient antecedent basis for this limitation in the claim.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 15-18, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stainmesse et al US 5,133,908. The claims are rejected for the reasons set forth in Paper No, 16 mailed 31 October 2003 and the Advisory mailed 09 March 2004. Applicants feel that Stainmesse et al does not teach or suggest all the claim limitations of the rejected claims (15-18, 22-25). "The examiner has not shown how the following limitation in the present rejected claims is taught or suggested by Stainmesse et al": "continuously in a mixing chamber by spraying the two components as a compact jet into a mixing chamber." It is noted that applicants disclose both a batchwise and a continuous process that are apparently equivalent. Page 9, lines 4-5. The use of one over the other does not constitute a patentable distinction. See MPEP 2144.04 (V.) E. *In re Dilnot*, 319 F.2d 188, 138, USPQ 248 (CCPA 1963) (Claim directed to a method of producing a cementitious structure wherein a stable air foam is introduced into a slurry of cementitious material differed from the prior art only in requiring the addition of the foam to be continuous. The court held the claimed continuous operation would have been obvious in light of the batch process of the prior art.).

11. Applicants feel the examiner has not shown there would be a reasonable expectation of success in modifying Stainmesse et al to teach or suggest the claimed invention. The references suggest commercial applications for the invention in medicine, pharmacy, agrochemistry, industry etc. Column 9, line 54 through column 10, line 30. It would reasonable to modify the process to continuous preparation to meet

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the needs for larger quantities required in industry. Regarding applicants' agitation limitation. Applicants state, "No person of ordinary skill in the art would be motivated to use "moderate agitation" for larger amounts to spray the two components as a compact jet into a mixing chamber." Applicants have disclosed both vigorous stirring or shaking or spraying as a means for mixing. All are apparently equivalent means for merely mixing the composition. While Stainmesse et al discloses moderate stirring and sometimes no stirring or agitation, example 1 discloses magnetic stirring at 100 r.p.m. Applicants' claim 1 does not have a mixing or agitation speed limitation. The scope of applicants' claims read on the prior art. No distinction is evident between applicants' mixing step and that of the prior art. The Roreger reference U.S. 6,761,908 B1 shows several conventional processing means including those at issue that are considered equivalent. Column 9, lines 11-24, claim 9. It would have been obvious to modify the Stainmesse et al process to continuous production using known means for mixing. The motivation being suggested by a desire to optimize production and tailor the mixing to yield the maximum quantity and quality of product for commercial use.

12. Claims 15-20 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over List et al U.S. 5,389,382. The claims are rejected for the reasons set forth in Paper No. 16, mailed 31 October 2003 and the Advisory Action, mailed 09 March 2004. Applicants have stated that List et al only relate to batch-wise production of the particle. Applicants' arguments are not convincing. As explained earlier it is the examiners position that applicants' limiting production to continuous or a compact jet does not constitute a patentable distinction as explained above. It is further noted that

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the comprising language of applicants' claims does not exclude a filtration step as disclosed in List et al. List et al states "any coarse particles which are precipitated are separated". This does not necessarily mean a required step for example 1. The scope of applicants' claims read on the prior art of record. It would be reasonable to modify the process of List et al using conventional continuous processing and mixing means. The motivation being suggested by a desire to provide the large quantities of commercial drugs such as cyclosporin, dihydropyridines, darodipine, progesterone, beclomethasone, Isradipine, etc. using a process that provides the greatest value to the consumer.

13. Claims 15-25 are rejected. Claims 1-14 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic  
Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "James M. Spear". The signature is fluid and cursive, with a large, sweeping flourish at the end.

James M Spear  
Primary Examiner  
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August 19, 2004